In the United States Court of Federal Claims

ALISHA N. PANKIW, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 15-vv-1082 Filed: August 13, 2021[1] Reissued for Public Availability: August 30, 2021

William E. Cochran, Jr., Black McLaren Jones Ryland & Griffee, PC., Memphis, Tennessee for Petitioner.

Sarah C. Duncan, United States Department of Justice, Civil Division, Torts Branch, Washington, D.C. for Respondent.

OPINION AND ORDER

On September 28, 2015, Petitioner Alisha N. Pankiw filed a Petition for compensation with the National Vaccine Injury Compensation Program, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2012) (Vaccine Act), for an off-table injury. Petition ¶ 1 (ECF No. 1). Specifically, Petitioner alleged that the flu vaccination administered on September 28, 2012 resulted in her developing inflammatory arthritis,[2] a condition that was

[1] Pursuant to the United States Court of Federal Claims Vaccine Rule 18(b), the Court filed this Opinion and Order on August 13, 2021, and provided the parties fourteen (14) days to propose redactions. The parties did not propose redactions. Accordingly, the Court is publicly reissuing its Opinion and Order in its original form for publication.

[2] Inflammatory arthritis is characterized by morning stiffness lasting more than an hour, "gelling" phenomena in which extended immobility such as from a car ride or getting out of a chair or tub leads to profound stiffness, fatigue, and elevated inflammatory markers. Pet'r Ex. 38 (ECF No. 64-2) (Dr. Utz's First Report) at 6.

resolved by September 5, 2013. *See* Petitioner's Motion for Review of Special Master's March 9, 2021 Decision Denying Compensation (ECF No. 118) (Pet'r Br.) at 6. Petitioner filed various medical records[3] and expert reports[4] to support her position. Respondent filed competing expert opinions[5] to support its position that Petitioner's joint pain was caused by postpartum autoimmune thyroiditis and not her September 28, 2012 flu vaccine.

On March 9, 2021, Special Master Christian J. Moran issued a decision concluding that Petitioner is not entitled to an award of compensation. *See Pankiw v. HHS*, No. 15-1082V, slip op. (Fed. Cl. Spec. Mstr. March 9, 2021) (ECF No. 116) (Dec. or Decision). The Petitioner seeks review of the Decision, contending that the Special Master erred in determining that Petitioner did not meet her burden of demonstrating causation under *Althen* prong one. Petitioner's Motion for a Ruling on the Record (ECF No. 113); *see also* Pet'r Br. Specifically, Petitioner alleges that the Special Master conducted his analysis under *Althen* prong one under the inaccurate premise that Petitioner was never diagnosed with inflammatory arthritis. Pet'r Br. at 6.

Respondent requests this Court affirm the Special Master's decision. Respondent's Response to Petitioner's Motion for Review (ECF No. 120) (Resp't Br.). Respondent argues the Special Master's findings regarding Petitioner's diagnosis are immaterial and that the Decision should be affirmed because Petitioner allegedly failed to provide a reliable medical theory causally

[3] Petitioner initially filed medical records marked as Exhibits 2-11 (ECF Nos. 9-10). She later filed additional medical records marked as Exhibits 15-18 (ECF No. 13) and expanded medical records marked as Exhibits 35-37 (ECF Nos. 42-43).

[4] Petitioner filed expert reports by Dr. Paul Utz (ECF Nos. 64, 74, 85, 95).

[5] Respondent filed reports by two experts: Dr. Mehrdad Matloubian (ECF Nos. 67, 78, 87, 102) and Dr. J. Lindsay Whitton (ECF No. 78-6).

connecting her flu vaccination to inflammatory arthritis or rheumatoid arthritis (RA). Resp't Br. at 13-16.

For the reasons stated below, Petitioner's Motion for Review is **SUSTAINED**. The Special Master's Decision denying entitlement is **VACATED**, and the case is **REMANDED** for further proceedings consistent with this Opinion and Order.

BACKGROUND

I. Petitioner's Medical Records

Petitioner is a 31-year-old female with a medical history that includes hyperthyroidism, thyroiditis, and significant back pain. Pet'r Ex. 16-1 (ECF No. 13-4) at 8-11; Pet'r Ex. 35 (ECF No. 42-2) at 5-10.[6] After giving birth in March 2012, Petitioner was diagnosed with low thyroid stimulating hormone (TSH). Pet'r Ex. 15 (ECF No. 13-3) at 86-87, 90-92; Pet'r Ex. 37 (ECF No. 43-3) at 5, 11. Additionally, Petitioner experienced lower and mid back pain, and ankle pain at least as early as March 2012. *See generally* Pet'r Ex. at 15 (chronicling "problems" of "low back pain syndrome" and "ankle pain"); Pet'r Ex. 35 at 5-8. On September 17, 2012, Petitioner visited Dr. Ernest Asamoah, an endocrinologist, regarding her low TSH. Pet'r Ex. 16-1 at 4. Dr. Asamoah found Petitioner's condition was "classic for post partum thyroiditis," and should be monitored to prevent the risk of hypothyroidism. Pet'r Ex. 16-1 at 9-10.

On September 28, 2012, Petitioner received the flu vaccine under the Fluarix brand. Pet'r Ex. 2 (ECF No. 9-1). Twelve days later, on October 10, 2012, Petitioner visited her primary care physician, Dr. William A. Heisel, and complained of "sharp" joint pain in her right ankle, a "swollen" left knee, and pain in her left middle toe and right index finger. Pet'r Ex. 6 (ECF No.

[6] This Court refers to the page numbers that CM/ECF automatically generates at the top of each page when referencing Petitioner's exhibits.

9-5) at 1, 4-5. During the examination, Dr. Heisel found "some arthritis" in Petitioner's right ankle but concluded that this was "not a typical presentation for rheumatoid arthritis," because her arthritis was not "symmetric." *Id*. at 5. On October 15, 2012, Petitioner revisited Dr. Heisel for swelling in her left knee that she characterized as "stiffness," which, she reported, had begun a month earlier and had recently worsened. *Id.* at 22. Dr. Heisel diagnosed Petitioner with acute arthritis. *Id*. at 23. Dr. Heisel noted that it was unlikely Petitioner's symptoms were caused by rheumatoid arthritis and that her post-partum status indicated that her symptoms were more likely the result of inflammatory arthritis. *Id.* Dr. Heisel treated Petitioner's symptoms with a steroid injection in her left knee. *Id.* at 22. On October 23, 2012, Petitioner attended a third appointment with Dr. Heisel, during which Petitioner reported reduced pain in her left knee, worsening pain in her right ankle, and no change in pain from her index finger and left third toe. *Id.* at 27-31. Dr. Heisel noted that RA was still "fairly unlikely." *Id.* at 31.

In early November of 2012, Petitioner discovered she was pregnant. Pet'r Ex. 12 at 1 (¶ 11). Petitioner subsequently visited several doctors complaining of joint pain. On November 8, 2012, Petitioner met with Dr. Kathleen Thomas, a rheumatologist, who noted that Petitioner recently had postpartum thyroiditis in early August 2012 and had developed joint symptoms soon thereafter. Pet'r Ex. 36 (ECF No. 43-2) at 9. Dr. Thomas reported that Petitioner had "unspecified inflammatory polyarthropathy" consistent with her thyroid disease and prescribed prednisone for symptomatic relief. *Id.* at 11-12. On November 12, 2012, Petitioner visited Dr. Cady Linn, an obstetrician-gynecologist, for prenatal treatment. Pet'r Ex. 8 (ECF No. 10-1) at 8. Dr. Linn noted that Petitioner was undergoing diagnosis for a possible rheumatologic condition. *Id.* Dr. Linn also noted that Petitioner had a "huge improvement in her left knee stiffness" since taking prednisone. *Id.*

On November 20, 2012, Dr. Asamoah increased Petitioner's Synthroid dose to treat her thyroiditis. Pet'r Ex. 16-1 at 21-27. On December 4, 2012, Petitioner followed up with Dr. Thomas for undifferentiated arthritis—complaining of joint pain in her left knee, right ankle, and right index finger. Pet'r Ex. 7 (ECF No. 9-6) at 3. During this visit, Dr. Thomas found that Petitioner's symptoms may be indicative of "early seronegative [rheumatoid arthritis]" but suggested Petitioner's ongoing pregnancy could complicate a diagnosis due to an "immunologic shift." *Id.* Dr. Thomas suggested Petitioner reduce her prednisone dosage over time and transition to Plaquenil in her third trimester. *Id.*

Dr. Linn referred Petitioner to Dr. Thomas Slama, an infectious disease specialist whom Petitioner visited on December 18, 2012. Pet'r Ex. 9 (ECF No. 10-2) at 43-44. During this visit, Dr. Slama observed that Petitioner had a "hot, swollen right ankle and left knee in addition to arthralgia of her left wrist." *Id.* On January 11, 2013, Dr. Slama referred Petitioner to Dr. Denise Thornberry. *Id.* at 20. In his referral letter, Dr. Slama stated that he had evaluated Petitioner's condition and found that Petitioner's active arthritis from the initial visit to be nearly resolved but stated that "[a]t the present time, all I can say is that [Petitioner] has an active synovitis that is not likely bacterial in etiology." *Id.*

On February 18, 2013, Petitioner visited Dr. Denise Thornberry, a rheumatologist, on referral from Dr. Slama. Pet'r Ex. 10 (ECF No. 10-3) at 27. In summarizing parts of Petitioner's medical history, Dr. Thornberry noted the pain and swelling Petitioner had experienced in her left knee, right ankle, left third toe, and right index finger. *Id.* While Petitioner's left toe pain was resolved, she still experienced pain in her right index finger Proximal interPhalangeal (PIP) joint, right ankle, and left knee. *Id*. at 50. Dr. Thornberry diagnosed Petitioner's condition as "[a]symmetric inflammatory polyarthritis associated with a positive ANA." *Id.* at 51.

Additionally, Dr. Thornberry noted "the distribution of [Ms. Pankiw's] articular disease is unusual for systemic lupus erythematosus (SLE) and rheumatoid arthritis." *Id*. Dr. Thornberry considered that Petitioner's ongoing pregnancy might have some influence on arthropathy levels. *Id.*

Petitioner reported improvements throughout her subsequent appointments with Dr. Thornberry. Petitioner returned to Dr. Thornberry on May 7, 2013 for a follow-up appointment regarding Petitioner's asymmetric pauciarticular inflammatory arthritis. *Id*. at 45. Petitioner complained of persistent swelling at her right ankle that was not painful. *Id.* She denied experiencing early morning stiffness. *Id.* Dr. Thornberry noted there was "slight swelling" of the right Achilles tendon; accordingly, he decreased her prednisone prescription to every other day for six weeks at the same dose of 2.5 mg. *Id.*

By September 5, 2013, Dr. Thornberry had determined that Petitioner's "[p]auciarticular inflammatory arthritis associated with positive ANA [was] resolved." Pet'r Ex. 10 at 42. On December 13, 2013, Petitioner called Dr. Thornberry requesting a written statement that Petitioner could not receive the flu vaccination due to her past symptoms of joint pain. *Id.* at 81. On January 20, 2014, Dr. Thornberry provided the requested letter, which stated that Petitioner "had a significant adverse reaction to an influenza vaccine administered in September 2012, manifested by arthritis." *Id.* at 41. On January 8, 2015, Petitioner returned to Dr. Thornberry and complained of continued joint pain during exercise. *Id*. at 16-17. Dr. Thornberry noted Petitioner had "joint pain without evidence of inflammatory arthritis" and the joint pain could be due, in part, to her "deconditioned state and overweight status." *Id*. at 17.

On May 29, 2015, in response to a request from Petitioner's attorney, Dr. Thornberry provided a summation of her treatment. *Id.* at 27-30. Dr. Thornberry identified Petitioner's diagnosis as "inflammatory arthritis associated with a positive ANA," that was resolved on

September 5, 2013. *Id*. at 28. Dr. Thornberry ultimately found that "[w]ith the asymmetric and pauci-articular nature of her illness, consistent with viral arthropathy or a vaccine-induced arthropathy, it was felt that there was reasonable medical probability that her symptoms were caused by the influenza vaccination." *Id.*

II. Expert Opinions

In addition to the referenced medical records, the Special Master reviewed eleven expert reports filed by three different experts. *See generally* Pet'r Ex. 38 (ECF. No. 64-2) (Dr Utz's First Report); Resp't Ex. A (ECF No. 67-1) (Dr. Matloubian's First Report); Pet'r Ex. 39 (ECF No. 74-2) (Dr. Utz's Second Report); Resp't Ex. C (ECF No. 78-1) (Dr. Matloubian's Second Report); Resp't Ex. D (ECF No. 78-6) (Dr. Whitton's First Report); Pet'r Ex. 39 (ECF No. 85-2) (Dr. Utz's Third Report); Resp't Ex. F (ECF No. 87-1) (Dr. Matloubian's Third Report); Pet'r Ex. 41 (ECF No. 95-1) (Dr. Utz's Fourth Report); Resp't Ex. G (ECF No. 87-7) (Dr. Whitton's Second Report); Resp't Ex. H (ECF No. 102-1) (Dr. Matloubian's Fourth Report); Resp't Ex. I (ECF No. 102-7) (Dr. Whitton's Third Report). These expert reports are discussed in more detail below.

A. Petitioner's Expert Reports

Petitioner retained Dr. Paul Utz, who serves as the Acting Chief of Rheumatology at Stanford University and who owns a lab that receives funding from the National Institute of Health to study influenza infection and vaccination. Pet'r Ex. 38 (Dr. Utz's First Report) (ECF. No. 64-2) at 1-2. Dr. Utz filed four reports.

On November 3, 2017, Petitioner filed her first expert report from Dr. Utz, who concluded that Petitioner had developed inflammatory arthritis as a "direct result" of her influenza vaccination. Pet'r Ex. 38 at 25. Dr. Utz theorized that it is "plausible" that the influenza vaccine can cause inflammatory arthritis when "influenza antigen(s) in the vaccine are delivered to the

immune system, leading to cross reactivity and molecular mimicry to self-antigens that then break tolerance to self, causing inflammatory arthritis." *Id.* at 11-12. Specifically, Dr. Utz described how hemagglutinin (HA), an antigen found in influenza vaccines, and Type II collagen, a prominent rheumatoid arthritis (RA) autoantigen, can lead to the development of B and T cell autoreactivity associated with inflammation. *Id.* at 16-17. According to Dr. Utz, an influenza peptide and a Type II collagen peptide bind to MHC/HLA class II molecule HLA-DR4 which affect T cell binding indirectly. *Id*. at 18-19. However, the studies used to support his research did not involve inflammatory arthritis and did not demonstrate that T cells recognize collagen or influenza peptides. *Id*. at 19-20. Still, Dr. Utz asserted that these studies suggest that such molecular processes can be generalizable to inflammatory arthritis and many of Petitioner's symptoms. *Id.* at 23-25.

On May 21, 2018, Dr. Utz defended his theory of molecular mimicry as a valid hypothesis noting that molecular mimicry is broadly accepted as a mechanism that leads to autoimmunity. Pet'r Ex. 39 (Dr. Utz's Second Report) (ECF No. 74-2) at 6. Dr. Utz reiterated that influenza HA and collagen antigens can bind to an MHC DR4 molecule and, as a result, share a similar composition and are molecular mimics of one another. *Id.* Dr. Utz emphasized that Petitioner's own rheumatologist, Dr. Thornberry, found Petitioner's symptoms "consistent with viral arthropathy or a vaccine-induced arthropathy, [and] . . . that there was a reasonable medical probability that her symptoms were caused by the influenza vaccination." *Id.* at 5 (quoting Pet'r Ex. 10 at 27-28).

On December 10, 2018, the Special Master issued an order for submissions in preparation for a hearing. In that order the Special Master stated, *inter alia*:

> Here, the parties agree that Ms. Pankiw's condition does not meet the generally-accepted criteria for rheumatoid arthritis ("RA"). Exhibit 38 at 8; exhibit

> A at 10. Nonetheless, Dr. Utz notes that Ms. Pankiw's inflammatory arthritis resembles many features of RA even if it does not meet the formal classification. Furthermore, Dr. Utz often uses RA and Ms. Pankiw's form of arthritis interchangeably in his argument that Ms. Pankiw has a vaccine-induced arthritic condition. In their responsive reports, Drs. Matloubian and Whitton appear to accept the premise that RA is, for the purposes of Ms. Pankiw's case, sufficiently similar to Ms. Pankiw's condition that it can be used interchangeably for the purposes of examining whether the flu vaccine can cause her current arthritic condition. Accordingly, there appears to be little dispute about the fact that Ms. Pankiw suffers from arthritis and that while her condition is not RA, RA is sufficiently similar to be used as a model for her condition.

Spec. Mstr. December 10, 2018 Order for Submissions in Preparation of the Hearing (ECF No. 84) (December 10, 2018 Order) at 4. In a footnote, the Special Master added, "[i]f the undersigned is incorrect in his conclusion that the parties agree that RA is a useful model for understanding Ms. Pankiw's current condition, they should explicitly address this mischaracterization in their briefs." *Id*. at 4 n.2.

On January 3, 2019, Dr. Utz filed a third expert report, which did not respond to the question the Special Master posed in his December 10, 2018 Order, but instead reiterated that an individual T cell receptor recognizes more than one peptide and that Petitioner's "abnormal" immune system was "primed" for molecular mimicry. Pet'r Ex. 40 (ECF No. 85-2) (Dr. Utz's Third Report) at 3-6.

Dr. Utz responded to the December 10, 2018 Order in his fourth and final response by noting that while Petitioner does not have RA, "the bystander activation and molecular mimicry models . . . apply broadly to other inflammatory arthritides." Pet'r Ex. 41 (Dr. Utz's Fourth Report) (ECF No. 95-1) at 13. Therefore, Dr. Utz concluded "to a reasonable degree of medical and scientific certainty that [Petitioner had] developed new onset inflammatory arthritis as a direct causative result of her influenza vaccination." Dr. Utz's Fourth Report at 21.

B. Respondent's Expert Reports

1. Dr. Matloubian's Reports

Respondent retained Dr. Mehrdad Matloubian, an Associate Professor at the University of California San Francisco and a board-certified rheumatologist who has been engaged in virology/immunology research for more than 20 years. Resp't Ex. A (ECF No. 67-1) (Dr. Matloubian's First Report) at 1. On February 5, 2018, Respondent filed an expert report by Dr. Matloubian, who opined that Petitioner's inflammatory arthritis was caused by her postpartum autoimmune thyroiditis, unrelated to the flu vaccine. Dr. Matloubian's First Report at 10, 23. Dr. Matloubian disagreed with Dr. Utz's medical theory based on molecular mimicry on the basis that (1) there are differences between the pathogenesis of RA and Petitioner's inflammatory arthritis, and (2) even if RA was sufficiently similar to Petitioner's inflammatory arthritis there was still no support for Dr. Utz's molecular mimicry theory linking the influenza vaccine and RA or any another type of inflammatory arthritis. *Id*. at 21-22.

On September 21, 2018, Dr. Matloubian submitted a second report maintaining that no evidence supported Dr. Utz's molecular mimicry theory. Resp't Ex. C (ECF No. 78-1) (Dr. Matloubian's Second Report) at 1. Notably, Dr. Matloubian stressed that a medical theory of causation based on molecular mimicry requires more than simply showing that two molecules are similar. *Id.* at 3. According to Dr. Matloubian, in the immunologic sense, molecular mimicry must show that two sperate antigens are activated by the same T cell. *Id.* Dr. Matloubian, criticized Dr. Utz's theory because, according to Dr. Matloubian, Dr. Utz purportedly failed to provide any support for the proposition that influenza HA and collagen can be recognized by the same T cell. *Id.* at 5.

On April 5, 2019, Dr. Matloubian again refuted Dr. Utz's molecular mimicry theory, stating that Dr. Utz has not shown that (1) collagen is an acceptable antigen in types of inflammatory arthritis other than RA, (2) T cells are generally able to recognize multiple peptides, and (3) influenza HA and collagen are similar enough to be cross-reactive. Resp't Ex. F (ECF No. 87-1) (Dr. Matloubian's Third Report) at 5-7.

On December 9, 2019, Dr. Matloubian filed his final response, which addressed the questions in the Special Master's December 10, 2018 Order. Resp't Ex. H (ECF No. 102-1) (Dr. Matloubian's Fourth Report) at 1. Dr. Matloubian stated there is no molecular mimicry between collagen, an RA-associated antigen, and influenza HA. *Id.* at 12. Dr. Matloubian argued that the expert reports offered by Dr. Utz do not demonstrate that "HA peptides can activate T cells that can cause arthritis." *Id.* at 13. Dr. Matloubian further criticized Dr. Utz's focus on HLA-DR4, "a molecule strongly associated with anti-CCP positive RA, but not with other forms of autoimmune arthritis." *Id.* at 19.

Therefore, Dr. Matloubian ultimately concluded that:

> In my professional duties, I would not interpret the papers provided by Dr. Utz on the altered peptide ligand as indicative of molecular mimicry between influenza HA and collagen, nor would I equate the complex pathogenesis of HLA-DR4-associated CCP positive RA to that of HLA-B27-associated spondyloarthropathies or all other types of inflammatory arthritis.

Dr. Matloubian's Fourth Report at 19.

2. Dr. Whitton's Reports

Respondent also offered three reports from Dr. J. Lindsay Whitton, a Professor at Scripps Research Institute who studies viral pathogenesis and the immune responses to virus infections and vaccines. Resp't Ex. E (ECF No. 78-7) (Dr. Whitton's curriculum vitae). Dr. Whitton agreed with Dr. Matloubian that Petitioner's inflammatory arthritis was not caused by her influenza

vaccination. *See generally* Resp't Ex. D (ECF No. 78-6) (Dr. Whitton's First Report); Resp't Ex. G (ECF No. 87-7) (Dr. Whitton's Second Report); Resp't Ex. I (ECF No. 102-7) (Dr. Whitton's Third Report). Dr. Whitton opined that Dr. Utz had not demonstrated that flu and collagen peptides are molecular mimics because he could not show that such peptides activate the same T cells. Dr. Whitton's First Report at 12. In his second report, Dr. Whitton acknowledged that T cells can recognize multiple antigens, but that this capability of recognizing multiple antigens was not as widespread as Dr. Utz's report implied. ECF No. 87-7 at 4-7. Dr. Whitton's third report was especially critical of Dr. Utz's purportedly selective reliance on certain studies and his allegedly shifting theory of molecular mechanisms, which he contended led to Petitioner's inflammatory arthritis. Dr. Whitton's Third Report at 1-2.

In each of his three expert reports, Dr. Whitton concluded that the evidence supporting Dr. Utz's theory that molecular mimicry was responsible for Petitioner's arthritis was "extremely weak." *Id.* at 14-15.

III. *Tullio v. Secretary of Health and Human Services*, 15-vv-15

On December 7, 2018, the Special Master held a status conference to discuss the possibility of holding a coordinated hearing with the petitioner in *Tullio v. Secretary of Health & Human Services*, 15-vv-15, an action that also involved a medical theory of causation premised on molecular mimicry. *See* December 10, 2018 Order. The record does not reflect that a joint hearing ever occurred.

On December 19, 2019, the Special Master issued a decision denying the *Tullio* petitioner's claim of entitlement to compensation. *Tullio v. Sec'y of Health & Hum. Servs.*, 149 Fed. Cl. 448, 454-55 (2020). Subsequently, the Special Master held a status conference in the present action to determine whether Petitioner's case involved factors that would distinguish it from *Tullio*. On

April 20, 2020, Petitioner filed a status report urging the Special Master to wait for a decision from the United States Court of Federal Claims in *Tullio* before considering next steps in her case. (ECF No. 105.)

On June 18, 2020, the Honorable Marian Blank Horn issued a decision in *Tullio* affirming the Special Master's ruling on entitlement and denying compensation to the petitioner in that case. *Tullio*, 149 Fed. Cl. at 478. After reviewing Judge Horn's opinion denying the motion for review in *Tullio*, Petitioner informed the Special Master that she would likely seek a ruling on the record from the Special Master and requested additional time to determine whether she would file any additional proof in support of her Petition. (ECF No. 110.)

On October 28, 2020, Petitioner submitted additional evidence concerning how the influenza virus could lead to arthritis. (ECF No. 112.) Specifically, Petitioner filed a case report entitled "Transient oligoarthritic of the lower extremity following influenza B virus infection: Case report." Pet'r Ex. 52 (ECF No. 112-1) (Bruck et al., Transient Oligoarthritic of the Lower Extremity Following Influenza B Virus Infection: Case Report, 8 PEDIATRIC RHEUMATOLOGY 4 (2010)). The case report stated:

> A 12-year-old girl developed influenza B virus infection proven by typical symptoms and detection of the virus in a nasopharyngeal swab by culture and PCR. Two weeks later she developed an otherwise unexplained transient oligoarthritis of small joints of the left foot. Influenza viruses may be a hitherto underappreciated cause of a post-infectious arthritis.

Id. at 1.

III. The Special Master's Decision

On December 21, 2020, Petitioner moved for a ruling on the record, arguing that she had proven all three *Althen* prongs and relying heavily on Dr. Thornberry's statements that "there was a reasonable medical probability that [Petitioner's] symptoms were caused by the influenza

vaccination." Petitioner's Motion for a Ruling on the Record (ECF No. 113) at 1 (quoting Pet'r Ex. 10 at 27-28).

Respondent countered, arguing that Petitioner had not met the *Althen* prongs because she did not offer a reliable medical theory establishing that her flu vaccine caused her inflammatory arthritis. Respondent's Response to Petitioner's Motion for a Ruling on the Record (ECF No. 114) at 1-2. Respondent further contended that Petitioner's medical theory was unreliable because Petitioner's expert had premised his medical theory on RA, which Petitioner conceded she did not have. *Id.* at 2 Moreover, Respondent noted that the Special Master recently had rejected Dr. Utz's molecular mimicry theory in *Tullio*, and that Petitioner failed to provide sufficient evidence demonstrating that her medical theory was reliable. *Id.* at 3. In a footnote, Respondent acknowledged that Dr. Thornberry attributed Petitioner's inflammatory arthritis to the flu vaccine but argued that the Special Master was not bound by Dr. Thornberry's statements, especially where Dr. Thornberry allegedly did not provide a medical theory, explain the logical sequence of causation, or address the temporal relationship between Petitioner's vaccine and her injury. *Id.* at 4 n.6.

On March 9, 2021, the Special Master issued a Decision denying compensation. *See* Decision. First, the Special Master found that Petitioner failed to show, by a preponderance of the evidence, that she suffered from RA. Dec. at 6. Specifically, the Special Master's decision states:

> This conspicuous lack of a diagnosis or expert opinion identifying Ms. Pankiw's symptoms as manifestations of RA is significant because Dr. Utz's asserted medical theory relies on evidence produced to show that flu vaccinations can cause rheumatoid arthritis. Additionally, even though Dr. Utz states in his report that the flu vaccine can cause RA or inflammatory arthritis, see exhibit 38 at 17, *Dr. Thornberry explicitly stated that Ms. Pankiw does not have inflammatory arthritis either*. Exhibit 10 at 16-17. It follows that, even if the undersigned were to accept Dr. Utz's medical theory, it is questionable how it would be applied to Ms. Pankiw's specific case, given that she did not suffer from RA and that there is evidence against a diagnosis of inflammatory arthritis as well. Citing to studies

> relevant to the flu vaccine-RA link, Dr. Utz states that "[i]t is plausible, and I would argue very likely, that similar molecular mechanisms are at play in Ms. Pankiw's case . . . causing inflammatory arthritis." Exhibit 38 at 11-12. However, Dr. Thornberry stated that Ms. Pankiw did not suffer from inflammatory arthritis. Exhibit 10 at 16-17. Dr. Utz goes on to analogize various causal relationships with foreign antigens that involve conditions, none of which are Ms. Pankiw's arthritis condition. Essentially, Dr. Utz's medical theory is premised on research and medical literature involving RA. According to Dr. Utz and Ms. Pankiw's medical providers, Ms. Pankiw never suffered from RA. Therefore, the evidence presented does not appear particularly informative, much less persuasive, with regard to Ms. Pankiw's particular circumstances. See Broekelschen, 618 F.3d at 1345 ("[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case[.]").

Dec. at 7 (brackets in original) (emphasis added).

Second, the Special Master determined that, even if Petitioner could show she had RA, she nevertheless failed to meet the requirements under *Althen* prong one because she could not provide a plausible medical theory causally connecting receipt of the influenza vaccination to RA. *Id*. at 7-9. Relying on *Tullio*, the Special Master highlighted that an identical medical theory based on molecular mimicry associated with RA was rejected. *Id.* Based on the expert opinions, the Special Master found "no substantial departure" from *Tullio*. *Id.* at 9. The Special Master found that *Althen* prong one was dispositive and that he therefore did not need to reach *Althen* prongs two or three. *Id.*

On April 7, 2021, Petitioner filed a Motion for Review of the Special Master's Decision denying her claim pursuant to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (Vaccine Rules). *See* Pet'r Br. at 1. Petitioner argues that the Special Master's determination that Petitioner had not demonstrated a diagnosis and had not met her burden of proof under *Althen* prong one were arbitrary and capricious. *Id.* at 4. To support these assertions, Petitioner highlights the Special Master's failure to consider: (1) Dr. Thornberry's diagnosis of inflammatory arthritis, a condition Dr. Thornberry stated was resolved by 2013, and (2) Dr.

Thornberry's statements that, in his opinion, Petitioner's flu vaccine caused her inflammatory arthritis. *Id.* at 6-9.

APPLICABLE STANDARD OF REVIEW

The National Childhood Vaccine Injury Act of 1986 (Vaccine Act) created the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 *et seq.*, to provide compensation to people found to be injured by certain vaccines. Congress established the Vaccine Act after lawsuits against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227-28 (2011). Petitions alleging injuries caused by a vaccine must be filed in the United States Court of Federal Claims, where a Special Master initially reviews and issues an initial decision on the petition. *Id*. at 228 (citing 42 U.S.C. § 300aa–11(a)(1)).

Under the Vaccine Act, the United States Court of Federal Claims reviews the Special Master's decision upon the filing of a Motion for Review of Decision of Special Master. 42 U.S.C. § 300aa–12(e). Upon such a review, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision;
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law; or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *accord* Vaccine Rule 27(c). The standards set forth in 42 U.S.C. § 300aa-12(e)(2)(B), "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Human Servs*., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). "Thus, the [United States Court of Federal Claims] judge reviews the

special master's decision essentially for legal error or factual arbitrariness." *Bradley v. Sec'y of Health & Human Servs.,* 991 F.2d 1570, 1574 (Fed. Cir. 1993).

DISCUSSION

Under the Vaccine Act, Petitioner may demonstrate eligibility for an award in two ways. *See* Munn, 970 F.2d at 865. Petitioner may either show that she suffered an injury listed on the Vaccine Injury Table within the requisite time period, in which causation is presumed (table injury), or she may demonstrate that her condition was caused-in-fact by the flu vaccine (off-table injury). *Capizzano v. Sec'y of Health & Human Serv.*, 440 F.3d 1317, 1320-21 (Fed. Cir. 2006) (citing *Munn*, 970 F.2d at 865; 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). As Petitioner alleges an off-table injury here, she must prove by a preponderance of the evidence that her vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In showing "that the vaccination brought about her injury," Petitioner must satisfy the three *Althen* prongs. Petitioner must show by a preponderance of the evidence:

(1) a medical theory causally connecting the vaccination and the injury;

(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and

(3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278; *see also Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1354-55 (Fed. Cir. 2019).

A special master's factual findings are reviewed under the arbitrary and capricious standard of review. *Althen*, 418 F.3d at 1278. The scope of this review is limited and is highly deferential. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1360 (Fed. Cir. 2000). Factual findings

of a special master must reflect a consideration of the relevant evidence of record, not be wholly implausible, and articulate a rational basis for the conclusion reached. *See, e.g.*, *Cedillo v. Sec'y of Health & Human Servs*., 617 F.3d 1328, 1338 (Fed. Cir. 2010); *Hines ex. rel. Sevier v. Sec'y of the Dep't of Health & Human Servs*., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

Nonetheless, a deferential standard of review "is not a rubber stamp." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1256 (Fed. Cir. 2011) (O'Malley, J., concurring-in-part, dissenting-in-part). A special master must "consider[ ] the relevant evidence of record, draw[ ] plausible inferences and articulate[ ] a rational basis for [his] decision . . . ." *Hines*, 940 F.2d at 1528); *see* 42 U.S.C. § 300aa–13(b)(1). The special master's findings of fact also must be "supported by substantial evidence." *Doe v. Secretary of Health & Human Servs*., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton by Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996), *on remand from Shalala v. Whitecotton*, 514 U.S. 268 (1995)). "[A] finder of fact generally is not required to itemize every piece of evidence on an issue and adopt or reject it. *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 540 (2011) (citations omitted). However, the special master cannot dismiss so much contrary evidence that it appears that the special master "simply failed to consider genuinely the evidentiary record . . . ." *Campbell v. Sec'y of Health & Human Servs*., 97 Fed. Cl. 650, 668 (2011).

While Petitioner claims she suffered inflammatory arthritis based on Dr. Thornberry's diagnosis, Pet'r Br. at 8-9, the Special Master began his Decision by incorrectly stating that Petitioner alleged she had RA. Dec. at 1. Further, the Special Master incorrectly stated in his Decision that "even though Dr. Utz states in his report that the flu vaccine can cause RA or inflammatory arthritis . . . , Dr. Thornberry explicitly stated that [Petitioner] does not have inflammatory arthritis." Dec. at 7 (citations omitted). However, the record reflects that Dr.

Thornberry actually did diagnose Petitioner with "asymmetric inflammatory polyarthritis associated with a positive ANA." Pet'r Ex. 10 at 51; *see also id.* at 27, 28, 29, 30, 42, 45. Dr. Thornberry explained:

> [Petitioner's] history at the initial visit on 02/18/2013 was that she had received an influenza vaccine on 09/28/2012. She developed pain and swelling of the left knee and her right ankle of such significance that by 10/14/2012, she had to ambulate with crutches. She had additional symptoms involving the left 3rd toe and the right index finger. Joint examination on that date was abnormal for painful motion at the index finger PIP joint on the right hand and restriction of motion at the left knee, and swelling at the right ankle. Review of evaluation which had been accomplished prior to the time of my initial evaluation was remarkable for a positive ANA and elevation of CRP. Fluid obtained from the left knee on 12/18/2012 was abnormal with a white cell count of 2583, indicating the presence of inflammation. Tests for rheumatoid arthritis were negative. I did perform additional laboratory studies including CBC, creatinine, C3, C4, anti-double stranded DNA antibodies, and antiphospholipid antibodies. Those studies returned with normal or negative findings. She was treated initially with prednisone 20 mg daily, which was able to be tapered and discontinued in 06/2013. I saw her on 09/05/2014, and her examination then was without evidence of inflammatory arthritis. *It was felt that she had recovered from the inflammatory arthritis.* Repeat testing of ANA antibody, which may be observed in patients with SLE or as a consequence of nonspecific stimulation of the immune system, was negative on 12/09/2013.

Pet'r Ex. 10 at 27 (emphasis added). In other words, reading Dr. Thornberry's statement in context demonstrates that Dr. Thornberry found that Petitioner had suffered and then recovered from inflammatory arthritis. Because the Special Master omitted this critical evidence, this Court is left with no choice but to find that the Special Master abused his discretion *See Mockzek v. Sec'y of Health and Human Servs*., 776 F. App'x. 671 (Fed. Cir. 2019) (reversing and remanding special master's "harsh result" in dismissing the plaintiff's petition under the Vaccine Act and holding the special master abused his discretion because petitioner's expert testimony and additional evidence were not facially insufficient for purposes of summary judgment); *J.H. v. Sec'y of Health and Human Servs.*, 123 Fed. Cl. 206 (2015) (vacating and remanding the action to the special master

holding special master abused his discretion where he failed to consider all medical records and mischaracterized the considered records).

Respondent argues that, even if the Special Master erred in concluding that Petitioner did not suffer from inflammatory arthritis, the error is harmless because the Special Master explicitly found that Petitioner's evidence failed to meet the *Althen's* first prong. Resp't Br. at 13-14. Specifically, the Special Master stated, "[e]ven if a determination were made that [Petitioner] suffered from rheumatoid arthritis or a condition sufficiently similar to the asserted medical theory applicable, [Petitioner] has failed to provide a persuasive medical theory showing that a flu vaccination can cause arthritis." Dec. at 7.

The problem with this argument is that the Court cannot determine on the record currently before it whether the Special Master accurately addressed Petitioner's particular circumstances. Though the Special Master broadly states that Petitioner's asserted medical theory fails to demonstrate how "flu vaccine can cause arthritis," the record reflects that the Special Master failed to acknowledge Dr. Thornberry's statements that Petitioner suffered from inflammatory arthritis. Moreover, the Special Master heavily relies on his previous decision in *Tullio*, without addressing the specific facts of Petitioner's case. *Tullio* involved a petitioner with a different diagnosis who received a different vaccine. *See Tullio*, 149 Fed. Cl. at 451. More importantly, in *Tullio*, none of the petitioner's treating physicians ever attributed the petitioner's diagnosis with the petitioner's vaccine. *Id.* at 476. Conversely, here, the record reflects evidence that Dr. Thornberry, Petitioner's treating physician, attributed Petitioner's alleged inflammatory arthritis to Petitioner's flu vaccine. Specifically, Dr Thornberry stated that Petitioner's inflammatory arthritis was "consistent with viral arthropathy or a vaccine-induced arthropathy," and that "it was felt that there was reasonable

medical probability that her symptoms were caused by the influenza vaccination." Pet'r Ex. 10 at 27-30.

The Court recognizes that there is evidence on the record that may ultimately support the Special Master's conclusion that Petitioner's condition was not caused by Petitioner's influenza vaccine. *See e.g.*, Dr. Matloubian's Fourth Report at 19; Dr. Whitton's Third Report at 1-2. The Court further recognizes that the Special Master is not bound by Dr. Thornberry's diagnosis and may very well reach the same conclusion on remand. *See* 42 U.S.C. § 300aa-13(b) ("Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."). This Court, however, cannot sustain the Special Master's Decision as is where it failed reflect and address the particular facts of Petitioner's case. *See Shapiro*, 101 Fed. Cl. at 540 (2011) (remanding case to special master where special master's factual finding was based on a "selective reading" of petitioner's medical records); *cf. Dobrydnev v. Sec'y of Health & Human Servs*., 566 F. App'x 976, 982 (2014) (affirming special master's causation findings where special master "explicitly acknowledged" favorable evidence to petitioner but nonetheless concluded the evidence was "outweighed" by other record evidence).

Nor can this Court conclude at this stage that the Decision's failure to accurately address Dr. Thornberry's diagnosis was harmless error. It is unclear whether the Special Master's *Althen* prong one analysis was premised on the assumption that Petitioner did not suffer from inflammatory arthritis. Dec. at 7. Though the Decision at times broadly references Petitioner's medical theory for "arthritis" or "a condition sufficiently similar to RA," the Court is unable to determine on the current record whether the Special Master's determination under *Althen* prong one would be different had he considered the full context of Dr. Thornberry's diagnosis. *Id.*

Finally, fundamental fairness forecloses this Court from affirming the Decision where it lacks sufficient analysis particular to this Petitioner's case. *See* 42 U.S.C. § 300aa-13(b)(1)(A) ("In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record . . . any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death . . . ."); Vaccine Rule 8(b)(1) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.").

While the Decision's failure to adequately address Dr. Thornberry's statements in context may have ultimately result in harmless error, this Court strongly believes that Plaintiff is entitled to a decision based on an accurate reflection of the record and her own medical diagnoses. The Court cannot sufficiently conduct its review without the Special Master's analysis in this regard. *Cf. Tadlock v. McDonough*, 5 F.4th 1327 (Fed. Cir. 2021) (finding, in the context of the United States Court of Appeals for Veterans Claims jurisdiction, a remand is the proper course of action where the fact finder fails to adequately consider evidence in the first instance). Accordingly, this Court remands this action to the Special Master to determine whether the *Althen* prongs are satisfied bearing in mind Dr. Thornberry's statements and diagnosis in their full context.

CONCLUSION

For the reasons stated above, Petitioner's Motion for Review (ECF No. 118) is **SUSTAINED**. The Special Master's Decision denying entitlement (ECF No. 116) is **VACATED**, and this case is **REMANDED** for further proceedings consistent with this Opinion and Order.

IT IS SO ORDERED.

s/Eleni M. Roumel
ELENI M. ROUMEL
Judge

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Washington, D.C.

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